REMARKS

Claim 1 has been amended. Claims 1-7 remain pending in the present application. Support for the amendments is found in the specification and claims as filed. Accordingly, the amendments do not constitute the addition of new matter. Reconsideration of the application in view of the foregoing amendments and following comments is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected Claims 1-7 under 35 U.S.C. § 112, second paragraph, for the recitation "a corresponding recombinant antigen or synthetic peptide" because the Examiner believes that recombinant antigens and synthetic peptides are not found in patient samples. The claims have been amended to clarify that the antibodies are "directed against an infectious agent associated with pathogenesis of cardiovascular disease or autoimmune disease or a corresponding recombinant antigen or synthetic peptide." Thus, it is now clear that the "corresponding recombinant antigen or synthetic peptide" is the target of the antibody, rather than in the sample.

The Examiner further believes that Claim 1 is confusing because the preamble of the claim does not correlate with the analysis of the detected result. The preamble and the last step have been amended to be in correspondence with each other.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 102

The Examiner rejected Claims 1-7 under 35 U.S.C. § 102(b) as being anticipated by Blaser et al. (U.S. Patent No. 5,200,344). Blaser et al. discloses an ELISA test for the diagnosis of infection with *Campylobacter jejuni* or *Campylobacter coli*.

The Examiner rejected Claims 1-7 under 35 U.S.C. § 102(b) as being anticipated by Goldstein et al. (U.S. Patent No. 5,103,836). Goldstein et al. discloses an ELISA test for detecting HIV antibody.

As amended, Claim 1 recites, *inter alia*, "A method for diagnosing a possibility of cardiovascular disease or autoimmune disease in a patient" in which "higher than normal levels of infectious agent antibodies indicate the possibility of cardiovascular disease or autoimmune disease." Support for this amendment can be found in the specification. The Background Section of the specification at pages 1-5 gives an extensive discussion of pathogens that are linked to cardiovascular disease and autoimmune disease. Further support can be found in the figures of the specification. Figures 1-3 compare antibody levels against autoantigens involved in cardiovascular disease and autoimmune disease in patients with cardiovascular disease, patients with autoimmune disease, and healthy controls. Both sets of patients had much higher antibody levels than the healthy controls. Accordingly, Claim 1 has been amended such that the claim is now directed to an infectious agent that is associated with pathogenesis of cardiovascular disease or autoimmune disease.

According to M.P.E.P. 2131.01, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Neither Blaser et al. nor Goldstein et al. disclose a method for diagnosing a presence or possibility of cardiovascular disease or autoimmune disease. The *Campylobacter jejuni* and *Campylobacter coli* disclosed by Blaser et al. are among the most common bacterial causes of diarrheal illness in the United States, and are not associated with cardiovascular disease or autoimmune disease. HIV, as disclosed in Goldstein et al., is the human immunodeficiency virus and is similarly not associated with cardiovascular disease or autoimmune disease. Since Blaser et al. and Goldstein et al. do not disclose infectious agents associated with pathogenesis of cardiovascular disease or autoimmune disease, Blaser et al. and Goldstein et al. do not anticipate the present claims.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 102(b).

Furthermore, the present claims are nonobvious in view of Blaser et al. and Goldstein et al. As discussed above, the infectious agents disclosed in these references are not implicated with cardiovascular disease and autoimmune disease. One skilled in the art would not be

motivated to diagnose a presence or possibility of cardiovascular disease or autoimmune disease in a patient based on the presence of antibodies to these agents. Accordingly, the claims as amended are patentable over the cited references.

CONCLUSION

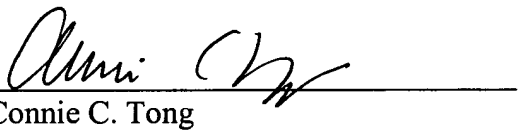
In view of the foregoing amendments and comments, it is respectfully submitted that the present application is fully in condition for allowance, and such action is earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned in order to resolve such issue promptly.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: October 13, 2004

By: 

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